SECTION 5 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

FEB 14 2014

5. 510(k) Summary of safety and effectiveness

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

APPLICANT:	Technolas Perfect Vision GmbH Messerschmittstr. 1 +3 80992 Munich, Germany Tel: 49 174 3494062
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TRADE NAME:	VICTUS Femtosecond Laser Platform
COMMON NAME:	Ophthalmic Laser
CLASSIFICATION NAME:	Laser, Ophthalmic
DEVICE CLASSIFICATION:	Class II
PRODUCT CODE	OOE (Ophthalmic Femtosecond Laser) HQF (Laser, Ophthalmic)
PREDICATE DEVICES:	VICTUS Femtosecond Laser Platform (K120426 and K122386) LenSx Laser System (K120732)

SUBSTANTIALLY EQUIVALENT TO

510(K) NUMBER	PRODUCT TRADE NAME	MANUFACTURER
K120426 K122386	VICTUS Femtosecond Laser Platform	Technolas Perfect Vision GmbH
K120732	LenSx Laser System	Alcon LenSx, Inc.

SECTION 5 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

Description of the Device Subject to Premarket Notification

The VICTUS Femtosecond Laser Platform (VICTUS) is a precision ophthalmic surgical laser and is cleared for use in the creation of a corneal flap in patients undergoing LASIK surgery or other treatment requiring initial lamellar resection of the cornea and for patients undergoing anterior capsulotomy during cataract surgery (via K120426). In addition, the VICTUS has been cleared for patients undergoing cataract surgery or other ophthalmic treatment requiring penetrating arcuate cuts / incisions in the cornea (via K122386).

This 510(k) expands the arcuate corneal incision indication by allowing the ability for primary and secondary corneal incisions. These cuts/incisions are performed for patients undergoing cataract surgery to allow direct access into the eye. The correct position and shape of the cuts is verified by the video image. The expansion of the corneal incision indication is supported by software version 2.7 SP2.

In addition, an increased diameter patient interface is being introduced (referred to as PI125). The PI125 is a universal PI that allows the use for either corneal or cataract procedures. User request for a smaller diameter patient interface that can be used for both cataract and corneal procedures resulted in the qualification of the existing cataract patient interface as a universal smaller diameter patient interface. Lastly, the bottom end of the pulse duration range has been modified to be lower than that previously cleared in K120426 and K122386.

For all indications for use, laser pulses are delivered through a sterile disposable Patient Interface, consisting of a contact lens and suction clip to provide suction. The contact lens and suction clip assembly creates a reference surface for depth control and fix the eye relative to the delivery of the laser beam. Surgical effects are produced by scanning thousands of individual pulses, producing continuous incisions. The location of the tissue photodisruption is controlled by a fixed laser beam focused through a scanning optic system to the desired location.

The fundamental scientific technology remains the same as previously cleared for the VICTUS Femtosecond Laser Platform under K120426 and K122386.

Indications for Use

The VICTUS Femtosecond Laser Platform is indicated for use for:

- the creation of a corneal flap in patients undergoing LASIK surgery or other treatment requiring initial lamellar resection of the cornea.
- for anterior capsulotomy during cataract surgery.
- the creation of cuts / incisions in the cornea in patients undergoing cataract surgery or other ophthalmic treatment requiring cuts / incisions in the cornea.

Technical Characteristics Comparison

The design principle of the VICTUS Platform is fundamentally the same as that previously cleared for VICTUS under K120426 and K122386. The VICTUS Platform mode of operation is the same as the previously cleared VICTUS Femtosecond Laser Platform cleared in K120426 and K122386, and the LenSx Laser System cleared in K120732, all of which deliver femtosecond pulses to produce a pattern of photodisruption to create cuts / separation in ophthalmic tissue. The VICTUS Platform delivers femtosecond pulses to produce a pattern of photodisruption for creation of primary and secondary cuts / incisions in the cornea, as does the LenSx predicate system.

The means of fixation of the patient contact portion of the VICTUS Platform is substantially equivalent to that present in the VICTUS Femtosecond Laser Platform cleared in K120426 and K122386, and the LenSx Laser cleared in K120732. All of these predicate systems use suction vacuum to affix a suction ring to the corneal surface prior to use.

The VICTUS Platform mode of operation and the technology used to create the cutting action are similar or identical to these previously mentioned devices, and therefore substantially equivalent to these legally marketed predicate devices.

Performance Data

The VICTUS Femtosecond Laser Platform has undergone testing and is in compliance with applicable safety standards as listed in the following table.

Standard	Title
EN ISO 60601-1	Medical electrical equipment – Part I: General requirements for safety
EN ISO 60601-1-2	Medical electrical equipment – Part 1: General requirements for safety; 2. Collateral standard: electromagnetic compatibility; requirements and tests
EN ISO 60601-1-4	Medical electrical equipment – Part 1-4: General requirements for safety; Collateral standard: Programmable electrical medical systems
EN ISO 60601-2-22	Medical electrical equipment – Part 2: Particular requirements for the safety of diagnostic and therapeutic laser equipment

The VICTUS Femtosecond Laser Platform has been found to perform equivalently to the predicate devices in patients undergoing ophthalmic surgery or other treatment requiring penetrating arcuate cuts / incisions in the cornea. The VICTUS Femtosecond Laser Platform and the predicate devices therefore have similar performance profiles.

Non-Clinical Performance Data

A variety of test procedures were conducted to demonstrate the performance of the modified VICTUS Platform in support of this premarket submission. The collected data were evaluated by comparing the mean values to the specified acceptance criteria and their 95% confidence intervals. Four different materials were used for the bench performance testing: porcine eyes, agarose gel, polyethylene terephthalate (PETG), and polymethyl methacrylate (PMMA). Testing was performed using the new larger diameter patient interface and results were substantially equivalent to the previously cleared patient interface. The new larger diameter patient interface is also representative for the existing cataract patient interface (use in corneal and cataract applications) as both have identical radius of curvature.

The testing showed that laser-assisted primary and secondary incisions performed with the VICTUS Femtosecond Laser Platform resulted in highly reproducible and accurate depth, diameter, and angle. Assessment of the larger diameter patient interface shows substantially equivalent results as compared to the predicate patient interfaces.

Basis for Determination of Substantial Equivalence

The technological characteristics of the VICTUS Femtosecond Laser Platform are substantially equivalent to the technological characteristics of the VICTUS Femtosecond Laser Platform (K120426 and K122386), and the LenSx Laser (K120732).

The proposed expansion of the indication for use of primary and secondary incisions for the VICTUS Femtosecond Laser Platform is very similar to the indications for use cleared for the LenSx Laser in K120732; both include creation of corneal cuts/incisions during cataract surgery.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 14, 2014

Technolas Perfect Vision GmbH
% Mr. Ken Nehmer
Sr. Manager, Regulatory Affairs, Americas
1025 Sanchez Street
San Francisco, CA 94114

Re: K132534
Trade/Device Name: VICTUS Femtosecond Laser System
Regulation Number: 21 CFR 886.4390
Regulation Name: Ophthalmic laser
Regulatory Class: II
Product Code: OOE, HQF
Dated: January 9, 2013
Received: January 10, 2013

Dear Mr. Nehmer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing

(21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kesia Y. Alexander -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K132534

Device Name: VICTUS Femtosecond Laser Platform

Indications For Use:

The VICTUS Femtosecond Laser Platform is indicated for use for:

- The creation of a corneal flap in patients undergoing LASIK surgery or other treatment requiring initial lamellar resection of the cornea
- For anterior capsulotomy during cataract surgery
- The creation of cuts / incisions in the cornea in patients undergoing cataract surgery or other ophthalmic treatment requiring cuts / incisions in the cornea.

Prescription Use___X___ AND/OR Over-The-Counter Use_____
(part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Ka N. To Date: 2014.02.11 17:18:48 -05'00'

(Division Sign-Off)
Division of Ophthalmic and Ear, Nose, and Throat Devices
510(k) Number: K132534